

Attorney Docket No.:

PENN-0798

Inventors:

Clevenger and Ryczyn

Serial No.:

09/647,139

Filing Date:

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REMARKS

Claims 7 and 8 are pending in the instant application. Claims 7 and 8 have been rejected. Claims 7 and 8 have been amended. No new matter has been added by these amendments to the claims. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejection of Claims Under 35 U.S.C. §112, First Paragraph

Claims 7 and 8 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The Examiner suggests that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner suggests that the specification does not indicate that cyclophilin B interaction with a somatolactogenic hormone is essential to any somatolactogenic function, and especially not more than one such function as required by the claims. The Examiner suggests that the nature of the invention is highly complex and although the specification provides teaching of the interaction of cyclophilin B with prolactin and growth hormone it fails to provide teaching of whether or not a compound that

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inhibits binding would affect a somatolactogenic function generally or even *in vitro* prolactin induced proliferation or nuclear translocation of prolactin, more specifically. The Examiner suggests it would require undue experimentation to practice the invention as claimed. Applicants respectfully traverse this rejection.

At the outset, Applicants have amended claim 7, and by dependency claim 8, to recite that the method of the instant invention is a method of identifying test compounds as inhibitors of somatolactogenic hormone-induced cell proliferation which comprises assessing the ability of a potential inhibitor compound to inhibit interaction of cyclophilin B with a somatolactogenic hormone, where inhibition of the interaction of cyclophilin B with the somatolactogenic hormone results in decreased levels of cell proliferation. Support for this amendment to the claims can be found throughout the specification as filed but in particular at pages 5-6 where it is taught that cyclophilin B and not cyclophilin A enhances the dose-dependent growth of cells in culture that is stimulated by prolactin.

As is discussed in the specification as filed, cyclophilin B increases prolactin driven cell growth or proliferation and does so in a dose-dependent manner (see teachings at page 6, lines 1-

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6. The dose-dependent nature of the effect indicates a specificity that involves a specific interaction of cyclophilin B with prolactin, not the involvement of another compound as is asserted by the Examiner. Further, as is taught in the specification as filed, prolactin cannot produce its actions in cells without the input of a chaperone protein, one such as cyclophilin B (see page 4, lines 13-16). Further, at page 6, lines 6-10, the action of cyclophilin B to enhance somatolactogenic function is described in even greater detail and shown to be related to cyclophilin B interacting with somatolactogenic hormones not other cytokines. Therefore, the specification as filed provides one of skill with specific evidence that the interaction of cyclophilin B with prolactin is necessary for induction or enhancement of cell proliferation or cell growth. One of skill would, therefore, understand that compounds that inhibit this interaction are then compounds that would inhibit prolactin-induced cell proliferation. This is a basic principle of pharmacology and toxicology where inhibitors are compounds that prevent specific interactions from occurring, acting in a dose-dependent manner. It would not require undue experimentation for one of skill to test compounds for their ability to inhibit cyclophilin B prolactin interactions in order

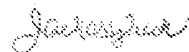
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to identify inhibitors of prolactin-induced cell proliferation. Accordingly, the claims as amended meet the requirements of 35 U.S.C. 112, first paragraph. Withdrawal of this rejection is respectfully requested.

II. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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